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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,535	10/12/2005	Josef Prassler	49981-012USNATL	8828
61263 7590 06/26/2008 PROSKAUER ROSE LLP 1001 PENNSYLVANIA AVE, N.W., SUITE 400 SOUTH WASHINGTON, DC 20004				
EXAMINER VOGEL, NANCY TREPTOW				
ART UNIT		PAPER NUMBER		
1636				
MAIL DATE		DELIVERY MODE		
06/26/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/522,535

Applicant(s)

PRASSLER ET AL.

Examiner

NANCY VOGEL

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF 298)
Paper No(s)/Mail Date ____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Claims 1-19 are pending in the case.

Sequence compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because sequences are set forth in the specification and drawings that lack sequence identifiers. It is often convenient to identify sequences in figures by amending the Brief Description of the Drawings section (see MPEP 244.02). If the sequences are already present in the sequence listing, it would be remedial to amend the Brief Description of the Drawings to include the appropriate sequence identifiers. Applicants are required to comply with all of the requirements of 37 CFR 1.821 - 1.825. Any response to this office action that fails to meet all of these requirements will be considered non-responsive. The nature of the noncompliance with the requirements of 37 C.F. R. 1.821 through 1.825 did not preclude the examination of the application on the merits, the results of which are communicated below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lohning (US 2002/0034733) in view of Burger et al. (Appl. Microbiol. Biotechnol. (1999) 52:345-353).

Lohning disclose phagemid vectors [0010] comprising a prokaryotic promoter (Fig. 16a) , a first nucleic acid sequence encoding an immunoglobulin-presenting polypeptide, which may be the phage coat protein gIII [0015] or fragment thereof [0017], a second nucleic acid sequence encoding a first Ig polypeptide, and a third nucleic acid sequence encoding a second Ig polypeptide [0050]. See Figs. 6a, 7a, 16a. A first and second associating agent are fused to or comprised within said Ig-presenting polypeptide and the first Ig polypeptide [0008, 0009, 0010]. The reference discloses that the first and second Ig polypeptides self-associate to form a Fab or other functional Ig fragment, via non-covalent interactions [0156]. The reference discloses that the first and second associating agents associate with each other via disulfide bond, and is a cysteine residue [0054]. The reference discloses prokaryotic secretory signal sequences in the same reading frame as each of the nucleic acid sequences [0156-0157]. The associating agents would become disassociated in solution upon the addition of a reducing agent [0070]. The vector comprises a ribosome binding site positioned 5' to the nucleic acid sequence encoding each of the first, second and third polypeptide, since it is shown in the reference that proteins are produced using the disclosed expression vectors, and therefore at least one ribosome binding site is present in the normal, 5' region of the start site of the polypeptide encoding region. The

reference exemplifies the use of two vectors, with one encoding the Ig presenting polypeptide pIII, and a bicistronic vector encoding the heavy and light chain, with each comprising a signal sequence upstream of the coding region, wherein the resultant Fab is linked to the pIII protein via disulfide bond (Example 2.2). The difference between the reference and the instant claims is that a single tricistronic vector carrying all components is not disclosed.

However, tricistronic vectors are known in the art as disclosed by Burger et al. Burger et al. disclose tri-cistronic vectors to achieve stable expression and/or secretion of three polypeptides of interest, two of which are Ig polypeptides (light chain and heavy chain). The reference discloses that a tricistronic vector is useful for "providing stability of expression which is a critical requirement for industrial scale production" (page 351). It would have been obvious to one of ordinary skill in the art to have used a tricistronic vector, as disclosed by Burger et al., to express the genes disclosed by Lohning, since both references are concerned with the expression of three different gene products simultaneously in an expression system. One would have been motivated to do so by the disclosure of Burger et al. of the usefulness of such vectors for obtaining stability of expression of three gene products. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is vague and indefinite in the recitation of "said first, second and secretory signal sequences are prokaryotic signal sequences". It is not clear what is intended by this phrase and therefore the intended metes and bounds cannot be determined.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY VOGEL whose telephone number is (571)272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NANCY VOGEL/
Primary Examiner, Art Unit 1636

NV
6/22/08